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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,779	01/02/2001	Gijsbert Johan Jansen	80541	4107

24628 7590 04/02/2007  
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EXAMINER
CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
1637	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/02/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/673,779	JANSEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Suryaprabha Chunduru	1637	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 January 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5-7,13-15 and 17-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7,13-15 and 17-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

1. The Applicants' response to the office action field on January 27, 2007 has been considered and acknowledged.

***Status of the Application***

2. Currently claims 1-3, 5-7, 13-15, 17-26 are pending. Claim 1 is amended. Claims 4, 8-12, 16 are cancelled. All arguments and amendment have been fully considered and deemed persuasive in part for the reasons that follow. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. The action is made FINAL.

***Response to arguments:***

3. With regard to the objection to the abstract of the instant disclosure, Applicants' amendment and arguments are fully considered and found unpersuasive. The objection is maintained herein because the amended abstract retains the form and legal phraseology 'said' in line 7-8 of the abstract.

4. With regard to the objection to the claims, Applicants' arguments are found unpersuasive. The objection is maintained as long as the scope of the claims remains the same.

5. With regard to the rejection of claims 1-3, 5-7, 13-15, and 17-22 under 35 USC 112, second paragraph, Applicants' arguments and amendment are fully considered and found persuasive. The rejection is withdrawn in view of the amendment.

6. With regard to the rejection of claims 1-3, 5-7, 13-14, 17-18, 20, 22, 23 under 35 USC 103(a) as being obvious over Welling et al. in view of Sheiness, Applicants' arguments are fully considered and found unpersuasive. Applicants argue that there is no teaching or suggestion to combine the cited references and the hindsight view of the Examiner's motivation to combine

cannot be sustained. Applicants also argue the disadvantages of the method of Welling et al. and assert that the advantages of the instant invention over the prior art and argue that welling et al. teaches away from the instant invention. Applicants' arguments are found unpersuasive. First, In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case Welling et al. does teach identification of microorganism using probes in in situ hybridization. Welling also teach the poor permeability of the probe is due to the gram positive nature of the microorganism, which is clearly a motivation to combine the method with the teachings of Sheiness. Second, with regard to the arguments based on the advantages of the instant invention, the arguments are found unpersuasive because as noted in *In re Aller*, 105 USPQ 233 at 235, More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the selection of hybridization conditions performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art. Applicants have not shown any unexpected results to rebut the advantages of the instant invention over the closest prior art of the record.

Applicants further argue that Sheiness does not remedy the deficiencies in Welling's reference. Applicants argue that Sheiness teach a gold standard lysis buffer containing various enzymes which includes lysozyme and lipase and teaches away from the present invention, which uses a lysis buffer containing at least lysozyme and lipase and assert that the combination cannot render the instant claims obvious. Applicants' arguments are found unpersuasive. With regard to the arguments based on teaching away MPEP 2145, "A prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness; however, "the nature of the teaching is highly relevant and must be weighed in substance. A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994), a teaching away, is a significant factor to be considered as "teaching in". In the instant context, Sheiness teaches a standard lysis solution comprising lysozyme and lipase among other enzymes present in the solution. Examiner notes no difference in said lysis buffer and the lysis buffer as recited in the instant claims because the 'lysis buffer containing' does not necessarily read on a lysis solution containing only those two enzymes, because the phrase solution containing is within the scope of an open comprising format, thus any unrecited elements are within the scope of the claimed solution. Applicants also argue that Examiner is picking and choosing from the prior art only so much as supports his position, to the exclusion of other parts necessary to full appreciation of what theses references fairly suggest to one of ordinary skill in the art and assert that the combination of references does not make the instant claims obvious. Applicants' arguments are found unpersuasive because obviousness does not require absolute predictability, only a reasonable

expectation of success; i.e. , a reasonable expectation of obtaining similar properties. See , e.g. , In re O'Farrell , 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).” In this factual case, there is express suggestion in the prior art that the gram-staining properties depend on the lysis conditions as taught by Sheiness. The is sufficient for a reasonable expectation of success. The MPEP cites In re O'Farrell, which notes regarding “obvious to try” at page 1682, that, In some cases, what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. E.g. , In re Geiger , 815 F.2d at 688, 2 USPQ2d at 1278; Novo Industri A/S v. Travenol Laboratories, Inc. , 677 F.2d 1202, 1208, 215 USPQ 412, 417 (7th Cir. 1982); In re Yates , 663 F.2d 1054, 1057, 211 USPQ 1149, 1151 (CCPA 1981); In re Antonie , 559 F.2d at 621, 195 USPQ at 8-9. In others, what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. In re Dow Chemical Co. , 837 F.2d, 469, 473, 5 USPQ2d 1529, 1532 (Fed. Cir. 1985); Hybritech, Inc. v. Monoclonal Antibodies, Inc. , 802 F.2d 1367, 1380, 231 USPQ 81, 90-91 (Fed. Cir. 1986), cert. denied , 107 S.Ct. 1606 (1987); In re Tomlinson ; 363 F.2d 928, 931, 150 USPQ 623, 626 (CCPA 1966). The court in O'Farrell then, affirming the rejection, notes “ Neither of these situations applies here.” For the instant case, it is clear that neither situations applies here either. This is not a situation where the prior art fails to identify the critical parameters. The prior art expressly teaches the parameters necessary for success. This is also not a situation where only general guidance was given. The prior art

provides specific guidance directing the use of the particular lysis buffer and lysis conditions that provide the identification of structural differences/ similarities of various bacteria.

Applicants' further argue that Sheiness does not teach detecting bacteria rather detect bacterial DNA and assert that Sheiness does not teach in situ hybridization and assert one of the ordinary skill in the art would not consider looking the lysis protocol as to the goal of in situ hybridization. Applicants' arguments are found unpersuasive. It is noted that gram-staining stains DNA not the bacterial cell as such. Thus the arguments based on detecting bacterial DNA does imply detecting a bacterium. Further the instant claims clearly recite hybridization of bacterial sample with a probe followed by differentiating the bacterial species based on gram-staining, which clearly does motivate one of ordinary skill in the art to consider the lysis protocol as the goal for hybridization, especially because Welling et al. clearly taught the poor permeability of the probe due to the gram-positive nature of the bacteria. One skilled in the art would use the lysis protocol as taught by Sheiness to distinguish the various types of bacteria based on the lysis or permeability of the cell wall of the bacteria with the lysis buffer to achieve better penetration of a probe into the cells.

Accordingly for the reasons above the rejection is maintained herein.

5. With regard to the rejection of claims 15, 19, 21, 24-25 under 35 USC 103(a) over Welling et al. in view of Sheiness, further in view of Hogan et al., Applicants' arguments are fully considered, and found unpersuasive. Applicants argue Hogan et al. does not teach in situ hybridization and argue that the differences between normal and in situ hybridization is ignored and the observation that a probe performs well in the context of a normal hybridization in the absence of any non-nucleic acid, material does not mean that the same probe is suited for in situ

hybridization, as other purposes and other characteristics of the probe are also important and assert that the general conditions of the claim 1 are not taught in the prior art and the prior art is not concerned with a coherent, simple and robust method not obvious over the prior art. Applicants' arguments are found unpersuasive because Hogan et al. is relied on hybridization probe SEQ ID Nos. 1-12) used as hybridization probes, some of the probes are also motioned in Welling's in situ hybridization protocol. The differences are not in the probe hybridization rather it is dependent on the penetration of the probe into the cell, reaching the DNA material. It is also note that there is no evidence or unexpected results provided by the Applicants to show that the probe selection is other than a routine optimization or the probes behave differently in normal and in situ hybridization assays. Accordingly the rejection is maintained herein. Examiner notes the preamble of the claim rejection did not include the claim 26.(SEQ ID Nos. 11 and 12). However, the body of the rejection addresses the limitations of the claim 26. Thus Examiner herewith treats that the rejection includes the claim 26.

***Conclusion***

No claims are allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37



CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru  
Primary Examiner  
Art Unit 1637

*Suryaprabha Chunduru*  
SURYAPRABHA CHUNDURU 3/28/07  
PRIMARY EXAMINER